

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Cynthia T. Clague et al.	Examiner:	Pavitra Kotini
Serial No.:	10/694,037	Group Art Unit:	3731
Filed:	October 27, 2003	Docket No.:	M190.242.101/P11210.00
Title:	METHOD AND APPARATUS FOR MAKING PRECISE INCISIONS IN BODY VESSELS		

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief – Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

This Appeal Brief is submitted in support of the Notice of Appeal filed on March 11, 2009, appealing the final rejection of claims 1-6, 15-23, and 32-34 of the above-identified application as set forth in the Final Office Action mailed December 11, 2008.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 50-0471 in the amount of \$540.00 for filing a Brief in Support of an Appeal as set forth under 37 C.F.R. § 41.20(b)(2). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 50-0471.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 1-6, 15-23, and 32-34.

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REAL PARTY IN INTEREST

The intellectual property embodied in the pending application is assigned to MEDTRONIC, INC.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present Appeal.

STATUS OF CLAIMS

Claims 1-46 are pending in the application. In the Notice of Panel Decision mailed April 14, 2009 and a Final Office Action mailed December 11, 2008, claims 1-6, 15-23, and 32-34 were finally rejected. Claims 7-14, 24-31, and 35-46 were withdrawn. No claims were cancelled. Claims 1-6, 15-23, and 32-34 are the subject of the present Appeal.

STATUS OF AMENDMENTS

In response to the Final Office Action mailed December 11, 2008 a Response was filed on February 11, 2009. No amendments were made in the Response filed February 11, 2009.

SUMMARY OF THE CLAIMED SUBJECT MATTER

I. Summary of Independent Claim 1

Claim 1 is directed to a vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel, such as a blood vessel, of a patient from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel (page 12, lines 1-4 of paragraph [0035]).

The instrument includes an elongated instrument shaft extending between a shaft proximal end and a shaft distal end and having an instrument shaft axis (page 23, lines 1-4 of paragraph [0087]). The elongated instrument shaft includes a fixed shaft member and a movable shaft member adapted to move with respect to the fixed shaft member in the direction of the instrument shaft axis (page 23, lines 5-6 of paragraph [0087] and lines 1-2 of paragraph [0089]).

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The instrument also includes a fixed cutting blade fixed to the fixed shaft member at the shaft distal end (page 23, lines 1-2 of paragraph [0088]). The fixed cutting blade extends laterally to the instrument shaft axis to a fixed cutting blade free end (page 23, lines 2-3 of paragraph [0088]). The fixed cutting blade includes a blunt distal leading blade side, a proximal, trailing side having a fixed cutting edge, and a cutting tip at the fixed cutting blade free end (page 23, lines 3-6 of paragraph [0088]).

The fixed cutting edge of the proximal trailing side is straight along the direction of the laterally extending fixed cutting blade. The blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, where the major portion extends perpendicular to the proximal trailing side (Figures 7 and 8, and page 23, lines 3-6 of paragraph [0088]).

The movable cutting blade includes a distal, leading edge fixed to the movable shaft member at the shaft distal end. The movable cutting blade extends laterally to the shaft axis and includes a movable cutting edge along the movable cutting blade distal, leading edge (page 23, lines 2-4 of paragraph [0089]).

The instrument also includes means for maintaining the movable shaft member in a retracted position with the movable cutting blade spaced proximally from the fixed cutting member as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel (pages 23-24, lines 5-8 of paragraph [0089]).

Still further, the instrument includes means for moving the movable shaft member with respect to the fixed shaft member between the retracted position separating the fixed and movable cutting edges and an extended position wherein the fixed and movable cutting edges are substantially in side-by-side alignment to shear the vessel wall and form a slit therein (page 24, lines 8-12 of paragraph [0089]).

II. Summary of Independent Claim 18

Claim 18 is directed vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient from an exterior surface to an interior

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surface of the vessel wall into a lumen of the body vessel (page 12, lines 1-4 of paragraph [0035]).

The instrument includes an elongated instrument shaft extending between a shaft proximal end and a shaft distal end and having an instrument shaft axis (page 23, lines 1-4 of paragraph [0087]). The elongated instrument shaft includes a first shaft member and a second shaft member adapted to move with respect to one another in the direction of the instrument shaft axis (page 23, lines 5-6 of paragraph [0087] and lines 1-2 of paragraph [0089]).

The instrument also includes a first cutting blade fixed to the first shaft member at the shaft distal end to extend laterally to the instrument shaft axis to a first cutting blade free end (page 23, lines 1-3 of paragraph [0088]). The first cutting blade includes a blunt distal leading blade side, a proximal, trailing side having a first cutting edge, and a cutting tip at the first cutting blade free end (page 23, lines 3-6 of paragraph [0088]).

The first cutting edge of the proximal trailing side is straight along the direction of the laterally extending first cutting blade. The blunt distal leading blade side includes a major portion spaced-apart from the cutting tip. The major portion extends generally perpendicular to the proximal trailing side (Figures 7 and 8, and page 23, lines 3-6 of paragraph [0088]).

The instrument also includes a second cutting blade having a distal, leading edge fixed to the second shaft member at the shaft distal end. The second cutting blade extends laterally to the shaft axis and includes a second cutting edge along the second cutting blade distal, leading edge (page 23, lines 2-4 of paragraph [0089]).

The instrument also includes means for maintaining the first and second shaft members in a retracted position with the second cutting blade spaced proximally from the first cutting blade as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel (page 23, lines 2-4 of paragraph [0089]).

Additionally, the instrument includes means for moving the first and second shaft members together from the retracted position to bring the first and second cutting edges substantially in side-by-side alignment to shear the vessel wall therebetween and form a slit therein (page 24, lines 8-12 of paragraph [0089]).

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GROUND S OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 1-3 and 18-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Shapiro U.S. Patent No. 5,314,440 in view of Taylor et al. U.S. Patent No. 6,387,108

II. Claims 4-6, 15-17, 21-23, and 32-34 stand rejected under 35 U.S.C. §103(a) Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,387,108 as applied to independent claims 1 and 18 above and further in view of the Taylor et al. US Patent No. 6,036,641.

ARGUMENT

I. The Applicable Law

With regard to a 35 U.S.C. § 103 obviousness rejection: “Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case.” M.P.E.P. 2141 (emphasis in the original). The Examiner bears the burden under 35 U.S.C. § 103 in establishing a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 [5 USPQ2d 1596, 1598] (Fed. Cir. 1988).

One criteria that must be satisfied to establish a *prima facie* case of obviousness is the reference or combined references must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981 [180 USPQ 580] (C.C.P.A. 1974).

However, “[a] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1731 [82 USPQ2d 1385, 1389] (2007). In making an obviousness determination over a combination of prior art references, it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.* at 1738 [1396].

In order to facilitate review of the determination of whether there was an apparent reason to combine known elements in the fashion claimed by the patent at issue, the “analysis should be made explicit.” *Id.* at 1738 [1396]. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (Fed. Cir. 2006) (cited with approval in *KSR*, 127 S. Ct. at 1738 [82 USPQ2d at 1396])

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The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 [227 USPQ 543, 551] (Fed. Cir. 1985). Furthermore, claims must be interpreted in light of the specification, claim language, other claims, and prosecution history. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 [1 USPQ2d 1593, 1597] (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). At the same time, a prior patent cited as a § 103 reference must be considered in its entirety, “*i.e.* as a *whole*, including portions that lead away from the invention.” *Id.* That is, the Examiner must recognize and consider not only the similarities, but also the critical differences between the claimed invention and the prior art as one of the factual inquiries pertinent to any obviousness inquiry under 35 U.S.C. § 103. *In re Bond*, 910 F.2d 831, 834 [15 USPQ2d 1566, 1568] (Fed. Cir. 1990) (emphasis added).

Furthermore, the Examiner must avoid hindsight. *Id.* “A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR*, 127 S. Ct. at 1739 [82 USPQ2d at 1397] (citing to *Graham v. John Deere*, 383 U.S. 1 [148 USPQ 459] (1966) in warning against a temptation to read into the prior art the teachings of the invention at issue and instructing courts to guard against slipping into the use of hindsight).

“[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR*, 127 S. Ct. at 1737 [82 USPQ2d at 1395] (citing to *United States v. Adams*, 383 U.S. 39, 51-52 [148 USPQ 479] (1966)).

In conclusion, an Appellant is entitled to a patent grant if a *prima facie* case of obviousness is not established. The Federal Circuit has endorsed this view in stating: “If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the Appellant is entitled to grant of the patent.” *In re Oetiker*, 977 F.2d 1443, 1446 [24 USPQ2d 1443, 1448] (Fed. Cir. 1992).

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II. Rejection of Claims 1-3 and 18-20 under 35 U.S.C. §103(a) as being unpatentable over Shapiro U.S. Patent No. 5,314,440 in view of Taylor et al. U.S. Patent No. 6,387,108.

Claims 1-3 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,387,108. Claims 1 and 18 are the two independent claims in this Appeal. Claims 2-6 and 15-17 depend from independent claim 1, and claims 19-24 and 32-34 depend from independent claim 18. Appellants will demonstrate that independent claim 1 and 18 include features not shown or made obvious in either Shapiro or Taylor and thus these features would be missing from any proposed combination of the references.

The final Office Action mailed December 11, 2008, (at page 4, paragraph number 9) states, “Shapiro discloses the invention substantially as claimed except for ‘the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side . . .’” as required in independent claims 1 and 18. This paragraph also states that Taylor discloses such a feature in Figure 6b. The Advisory Action mailed April 14, 2009, (at paragraph 11) further defines the rejection where it states, “Shapiro already discloses a moving blade 74 cooperatively with fixed blade 72. Examiner was relied on the teaching of a moving blade and a fixedly that have a design of the cutting edge of the proximal trailing side is generally straight along the direction of the laterally as disclosed by Taylor to modify the shape of the blades of Shapiro.”

Taylor, however, does not teach or make obvious the above-quoted claim features missing from Shapiro including “the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade.” Taylor only teaches using a hook-shaped design for the fixed blade stop 16 rather than the missing claimed features including “generally straight along the direction of the laterally extending fixed cutting blade.” Taylor teaches the upper surface 17 of the blade stop 16 is *hooked* in shape (concavely curved) and is not “*straight* along the direction of the laterally extending fixed cutting blade” (emphasis supplied). The fixed blade stops in Figures 5 and 6a of

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Taylor, which relate to the embodiment in Figure 6b, are also concavely-curved or hooked-shaped rather than “straight along the direction of the laterally extending fixed cutting blade” as claimed.

Because neither reference teaches the claimed features of “generally straight along the direction of the laterally extending fixed cutting blade,” this feature cannot be found in any proposed combination of the reference. Accordingly, Appellants request removal of the rejection of claims 1 and 18.

The prior art also does not suggest a modification to Shapiro or to Taylor to obtain the features of the present claims. As set forth in the Background section of the present application at paragraph [0031], the issues with curved blades or blade stops similar to a curved sewing needle is that

The slit length is dependent on the depth (“bite of tissue”) that the tip is inserted into the vessel lumen before the cutting blade or stop is turned back through the arterial wall. The distance along the artery from the insertion point to the exit point is dependent on how deep the tip is inserted into the arterial lumen and how quickly it is turned to position it at the exit point. The depth of the insertion is dependent upon the arterial lumen diameter.

The background section also discusses the problem with such hooked-shaped blades. For example, the slit length will be too short if the insertion depth is too shallow, which would require extending the slit by either repeating the procedure or using another instrument. Further, the slit length will be too long if the insertion depth is too deep, which would require probing the sharp tip about the inner surface of the arterial wall to determine the proper length. Such probing could cause damage to the endothelial layer of the vessel.

The designs of the prior art differ from the independent claims in part because the methods for making the incisions are different from each other. Shapiro and Taylor concern themselves with a device to make an incision in the vessel as approached from above the vessel, or from a direction generally perpendicular to a vessel axis. A hook-shaped design is used for this approach. No other method of making an incision is disclosed or contemplated in the references. On the other hand, the problems of the prior art are addressed in the independent claims as a result of a new method to make an incision in the vessel as approached from a direction generally in line with the vessel axis. Because the prior art does

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not recognize any other method other than the perpendicular approach, the present claims would not be obvious in view of the hook-shaped blades.

Taylor also does not teach or make obvious the above-quoted claim features missing from Shapiro including “wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side.” The blade stop of Taylor is essentially the same width through its length and no major portion is space-apart from the tip to meet these claim features. The claimed feature is missing from Shapiro and Taylor separately and thus cannot be found in any proposed combination of the references.

The prior art does not recognize the problem solved by this claimed feature and does not suggest a solution. The tip of Shapiro resides in generally the plane of the leading distal edge rather than the trailing proximal edge as required in the claims. The distinction being that tip of Shapiro can catch on the bottom of the vessel wall when the blade is in contact with the vessel wall. Under the features of the present claims, the disadvantages of Shapiro can be avoided. There is nothing in the teachings or suggestions of Shapiro or Taylor to suggest a configuration to avoid this problem. The prior art does not recognize the problems facing application or a novel method to correct these problem, the prior art does not make obvious any modifications of the standard hook-shaped blade surface to obtain the claimed features of “generally straight along the direction of the laterally extending fixed cutting blade.” Further, the prior art does not make obvious the modification of a blade on the distal leading edge and a blade stop of general uniform thickness to obtain the claimed features of “wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side.” Accordingly, Appellants request removal of the rejection of independent claims 1 and 18.

Claims 2-6 and 15-17, and claims 19-24 and 32-34 depend from independent claim 1 and 18 respectively. They contain all of the limitations of the independent claim and, by virtue of their dependency, are also patentably distinguishable from the prior art for the reasons described above. Accordingly, Appellants respectfully request removal of the rejection of independent claims 1 and 18, as well as dependent claims 2-6, 15-17, 19-24, and 32-34.

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III. Rejection of Claims 4-6, 15-17, 21-23, and 32-34 under 35 U.S.C. §103(a) over Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,387,108 as applied to independent claims 1 and 18 above and further in view of the Taylor et al. US Patent No. 6,036,641

Claims 4-6, 15-17, 21-23, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,387,108 as applied to independent claims 1 and 18 above and further in view of the Taylor et al. US Patent No. 6,036,641.

As discussed above, any proposed combination of Shapiro and Taylor ('108) will not teach all of the limitations of the claims, particularly the features of "the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side." Taylor ('641) teaches a device for stabilizing surgical instruments against a beating heart. Taylor does not teach or make obvious anything about a cutter configured as set forth in the claims. Thus, because the above quoted claimed features are not taught or made obvious in the prior art references of Shapiro, Taylor ('108), or Taylor ('641), the features would be missing from any proposed combination of the three references. Thus, Applicants respectfully request removal of the rejections of claims 4-6, 15-17, 21-23, and 32-34 based on the combination of Shapiro, Taylor ('108), and Taylor ('641) and also request allowance of these claims.

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CLAIMS APPENDIX

1. A vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising:

an elongated instrument shaft extending between a shaft proximal end and a shaft distal end and having an instrument shaft axis the elongated instrument shaft comprising a fixed shaft member and a movable shaft member adapted to move with respect to the fixed shaft member in the direction of the instrument shaft axis;

a fixed cutting blade fixed to the fixed shaft member at the shaft distal end to extend substantially laterally to the instrument shaft axis to a fixed cutting blade free end, the fixed cutting blade having a blunt distal leading blade side, a proximal, trailing side having a fixed cutting edge, and a cutting tip at the fixed cutting blade free end;

wherein the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side;

a movable cutting blade having a distal, leading edge fixed to the movable shaft member at the shaft distal end, the movable cutting blade extending substantially laterally to the shaft axis and having a movable cutting edge along the movable cutting blade distal, leading edge;

means for maintaining the movable shaft member in a retracted position with the movable cutting blade spaced proximally from the fixed cutting member as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel; and

means for moving the movable shaft member with respect to the fixed shaft member between the retracted position separating the fixed and movable cutting edges and an extended position wherein the fixed and movable cutting edges are substantially in side-by-side alignment to shear the vessel wall and form a slit therein.

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2. The vessel wall cutting instrument of Claim 1, wherein:

the fixed cutting blade is disposed to extend laterally to the shaft axis by a shank having a shank proximal end mounted to the fixed shaft member at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the movable cutting blade to a shank distal end; and

the fixed cutting blade extends laterally to the shaft axis from the shank distal end to the fixed cutting blade free end and has a substantially straight fixed cutting edge,

whereby the cutting tip at the fixed cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel.

3. The vessel wall cutting instrument of Claim 2, wherein:

the means for maintaining the movable shaft member in a retracted position comprises a spring mounted between the fixed shaft member and the movable shaft member and exerting retraction force therebetween; and

the moving means comprises means for transmitting force overcoming the retraction force to the movable shaft member to move the movable shaft member with respect to the fixed shaft member between the retracted position and the extended position.

4. The vessel wall cutting instrument of Claim 2, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

5. The vessel wall cutting instrument of Claim 2, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

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6. The vessel wall cutting instrument of Claim 2, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

7. (Withdrawn) The vessel wall cutting instrument of Claim 2, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the movable shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to overcome the retraction force.

8. (Withdrawn) The vessel wall cutting instrument of Claim 7, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

9. (Withdrawn) The vessel wall cutting instrument of Claim 7, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

10. (Withdrawn) The vessel wall cutting instrument of Claim 7, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

11. (Withdrawn) The vessel wall cutting instrument of Claim 1, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the movable shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to move the movable shaft member with respect to the fixed shaft member between the retracted position and the extended position.

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12. (Withdrawn) The vessel wall cutting instrument of Claim 11, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

13. (Withdrawn) The vessel wall cutting instrument of Claim 11, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

14. (Withdrawn) The vessel wall cutting instrument of Claim 11, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

15. The vessel wall cutting instrument of Claim 1, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

16. The vessel wall cutting instrument of Claim 1, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

17. The vessel wall cutting instrument of Claim 1, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

18. A vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising:

an elongated instrument shaft extending between a shaft proximal end and a shaft distal end and having an instrument shaft axis the elongated instrument shaft comprising

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a first shaft member and a second shaft member adapted to move with respect to one another in the direction of the instrument shaft axis;

a first cutting blade fixed to the first shaft member at the shaft distal end to extend substantially laterally to the instrument shaft axis to a first cutting blade free end, the first cutting blade having a blunt distal leading blade side, a proximal, trailing side having a first cutting edge, and a cutting tip at the first cutting blade free end;

wherein the first cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending first cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side;

a second cutting blade having a distal, leading edge fixed to the second shaft member at the shaft distal end, the second cutting blade extending substantially laterally to the shaft axis and having a second cutting edge along the second cutting blade distal, leading edge;

means for maintaining the first and second shaft members in a retracted position with the second cutting blade spaced proximally from the first cutting blade as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel; and

means for moving the first and second shaft members together from the retracted position to bring the first and second cutting edges substantially in side-by-side alignment to shear the vessel wall therebetween and form a slit therein.

19. The vessel wall cutting instrument of Claim 18, wherein:

the first cutting blade is disposed to extend laterally to the shaft axis by a shank having a shank proximal end mounted to the first shaft member at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the second cutting blade to a shank distal end; and

the first cutting blade extends laterally to the shaft axis from the shank distal end to the first cutting blade free end and has a substantially straight first cutting edge,

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whereby the cutting tip at the first cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel.

20. The vessel wall cutting instrument of Claim 19, wherein:

the means for maintaining the first and second shaft members in a retracted position comprises a spring mounted between the first shaft member and the second shaft member and exerting retraction force therebetween; and

the moving means comprises means for transmitting force overcoming the retraction force to move the second shaft member with respect to the fixed shaft member between the retracted position and the extended position.

21. The vessel wall cutting instrument of Claim 19, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

22. The vessel wall cutting instrument of Claim 19, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

23. The vessel wall cutting instrument of Claim 19, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

24. (Withdrawn) The vessel wall cutting instrument of Claim 19, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the second shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to overcome the retraction force.

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25. (Withdrawn) The vessel wall cutting instrument of Claim 24, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

26. (Withdrawn) The vessel wall cutting instrument of Claim 24, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

27. (Withdrawn) The vessel wall cutting instrument of Claim 24, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

28. (Withdrawn) The vessel wall cutting instrument of Claim 18, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the second shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to move the second shaft member with respect to the first shaft member between the retracted position and the extended position.

29. (Withdrawn) The vessel wall cutting instrument of Claim 28, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

30. (Withdrawn) The vessel wall cutting instrument of Claim 28, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

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31. (Withdrawn) The vessel wall cutting instrument of Claim 28, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

32. (Original) The vessel wall cutting instrument of Claim 18, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

33. The vessel wall cutting instrument of Claim 18, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

34. The vessel wall cutting instrument of Claim 18, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

35. (Withdrawn) A method of making an elongated slit through a vessel wall and into a lumen of a body vessel of a patient substantially in alignment with the axis of the body vessel comprising the steps of:

providing a vessel wall cutting instrument having first and second cutting blades, wherein the first cutting blade has a substantially straight first cutting edge extending along a trailing side of the first cutting blade, a cutting tip at the first cutting blade free end, and an atraumatic blunt surface along the leading side of the first cutting blade, and the second cutting blade has a second cutting edge extending along a leading side of the second cutting blade;

obtaining access to an exposed exterior surface of the vessel wall;

separating the first and second cutting blades apart;

advancing the blunt leading side of the first cutting blade against the exposed exterior surface of the vessel wall substantially in alignment with the vessel wall axis to depress the vessel wall and dispose a cutting tip of the first cutting blade against the exposed exterior surface of the depressed vessel wall;

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moving the first cutting blade laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel substantially in alignment with the vessel axis;

applying the first cutting edge of the first cutting blade against an interior surface of the vessel wall substantially in alignment with the vessel lumen; and

moving the first and second cutting edges substantially in side-by-side alignment to shear the vessel wall therebetween and form a slit therein.

36. (Withdrawn) The method of Claim 35, wherein the moving step further comprises moving the second cutting blade toward and alongside the first cutting blade as the first cutting edge of the first cutting blade is applied against an interior surface of the vessel wall substantially in alignment with the vessel lumen.

37. (Withdrawn) The method of Claim 36, further comprising applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

38. (Withdrawn) The method of Claim 36, further comprising applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

39. (Withdrawn) The method of Claim 36, further comprising applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

40. (Withdrawn) The method of Claim 35, further comprising applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

41. (Withdrawn) The method of Claim 35, further comprising applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

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42. (Withdrawn) The method of Claim 35, further comprising applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

43. (Withdrawn) The method of Claim 35, wherein the body vessel is a coronary artery extending along the epicardium of the heart.

44. (Withdrawn) The method of Claim 43, further comprising applying suction to the epicardium alongside the coronary artery to stabilize the coronary artery from movement of the heart.

45. (Withdrawn) The method of Claim 43, further comprising applying compressive force to the epicardium alongside the coronary artery to stabilize the coronary artery from movement of the heart.

46. (Withdrawn) The method of Claim 43, further comprising applying an occlusion frame against the coronary artery and epicardium alongside the coronary artery to compress the coronary artery lumen and inhibit blood loss through the elongated slit.

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EVIDENCE APPENDIX

None

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RELATED PROCEEDINGS APPENDIX

None

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CONCLUSION

For the above reasons, Appellants respectfully submit that the cited references neither anticipate nor render obvious claims of the pending Application. The pending claims distinguish over the cited references, and therefore, Appellants respectfully submit that the rejections be withdrawn, and respectfully request the Examiner be reversed and claims 1-6, 15-23 and 32-34 be allowed.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

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